

REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action. Our cheque in respect of the prescribed fee is enclosed.

The Examiner's specific withdrawal of the rejection of claims 1 to 29, 31 to 38 and 40 to 42 under 35 USC 112, first paragraph, with respect to the written description, is gratefully acknowledged.

The Examiner rejected claims 1 to 9, 13 to 23, 27 to 34 and 39 to 42 under 35 USC 112, first paragraph, on the basis that the specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Examiner acknowledged the specification is enabling for:

- 1) An immunogenic composition comprising a plasmid that will not replicate, wherein the plasmid comprises: a first nucleotide sequence encoding a respiratory syncytial virus (RSV) G protein or a RSV G protein fragment thereof, a cytomegalovirus promoter sequence operatively linked to the first nucleotide sequence for expression of the RSV G protein or fragment thereof, and a second nucleotide sequence encoding the human cytomegalovirus Intron A located between the first nucleotide sequence and the promoter sequence to increase expression of the RSV G protein or fragment thereof. Claim 1 has been amended to utilize language consistent with the enablement found by the Examiner.
- 2) A method of stimulating an immune response in a mammal using an effective amount of the composition of 1. Claim 15 has been amended to utilize language consistent with the enablement found by the Examiner. Claim 29 has been deleted.
- 3) A method for using a gene encoding a RSV G protein or a fragment thereof to produce an immunogenic composition, comprising the following steps: a) isolating a gene encoding a RSV G protein or a RSV G fragment thereof; b) operatively linking the gene or fragment thereof to an cytomegalovirus promoter sequence to produce a plasmid vector that will not replicate when introduced into a mammal; and c) introducing a second nucleotide sequence encoding the human cytomegalovirus Intron A into the plasmid from step b) between the

first nucleotide sequence and the promoter sequence to increase expression of the RSV G protein or fragment thereof, thereby producing an immunogenic composition. Claim 30 has been amended to utilize language consistent with the enablement found by the Examiner.

4) A method of administering the composition from step (c) of 3 to a mammal, to stimulate an immune response in said mammal. New claim 43 has been added, dependent on claim 30, directed to this enabled subject matter. Claims 40 to 42 have been cancelled.

Since the claims of the application now are directed to the scope of enablement found by the Examiner, as set forth in the Office Action, it is submitted that all claims are fully enabled by the disclosure and hence the rejection of claims 1 to 9, 13 to 23, 27 to 34 and 39 to 42, insofar as they remain in the application and in their amended form, under 35 USC 112, first paragraph, for lack of enablement, should be withdrawn.

The revisions made to the claims are intended to reflect the enablement indicated by the Examiner. In the event the Examiner considers that further revisions are required to the claims to place them in an allowable form, the Examiner is urged to contact the applicant's representative, Mr. Michael Stewart, collect, at the number given below, with a view to arriving at mutually-acceptable language.

Entry of the Amendment after Final Action is requested in that the application thereby is placed in completion for allowance. In the event the Examiner considers the rejection to remain, it is submitted that the Amendment nevertheless should be entered, in that the claims thereby are placed in better condition for appeal.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Michael I. Stewart", is positioned above a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 29 and 40 to 42.

Please amend claims 1, 15 and 30 as follows:

1. (Twice Amended) An immunogenic composition, [for *in vivo* administration to a host for the generation in the host of protective antibodies to respiratory syncytial virus (RSV) protein] comprising a plasmid [vector] which will not replicate, wherein the plasmid comprises [when introduced into the host to be protected comprising]:
 - a first nucleotide sequence encoding a respiratory syncytial virus (RSV) G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,
 - an immediate early cytomegalovirus promoter sequence operatively linked [coupled] to said first nucleotide sequence for expression of said RSV G protein or fragment thereof [in the host], and
 - a second nucleotide sequence encoding the human cytomegalovirus Intron A located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein or fragment thereof [*in vivo* from said vector in the host]; and
 - a pharmaceutically-acceptable carrier therefor.
15. (Twice Amended) A method of stimulating an immune response in a mammal using [immunizing a host against disease caused by infection with respiratory syncytial virus (RSV), which comprises administering to said host] an effective amount of an immunogenic composition comprising a plasmid [vector] that will not replicate, wherein the plasmid comprises [when introduced into the host to be protected comprising]:
 - a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,
 - an immediate early cytomegalovirus promoter sequence operatively linked [coupled] to said first nucleotide sequence for expression of said RSV G protein or fragment thereof in the host, [and]

a second nucleotide sequence encoding the human cytomegalovirus Intron A located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein or fragment thereof, and [in vivo from said vector in the host.]

a pharmaceutically-acceptable carrier therefor.

30. (Twice Amended) A method of using a gene encoding a respiratory syncytial virus (RSV) G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein, to produce immunogenic composition [an immune response in a host], which comprises:

(a) isolating said gene,

(b) operatively linking said gene or fragment thereof to an immediate early cytomegalovirus promoter sequence to produce a plasmid vector that will not replicate when introduced into a mammal, and [the host to be protected, said promoter sequence directing expression of said RSV G protein or fragment thereof when introduced into a host to produce an immune response to said RSV G protein or fragment thereof,]

(c) introducing a second nucleotide [into said vector an immunoprotection containing] sequence encoding the human cytomegalovirus Intron A into the plasmid from step (b) between said promoter sequence and said gene to increase expression of RSV G protein or fragment thereof, thereby producing an immunogenic composition], and

introducing said vector into a host].

Add new claim 43 as follows:

43. (New) The method of claim 30 further comprising administering the composition from step (c) to a mammal to stimulate an immune response in said animal.